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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,615	06/26/2001	Gregory Plowman	038602-1214	8543

7590 08/19/2004  
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EXAMINER

BORIN, MICHAEL L

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 08/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/888,615

**Applicant(s)**

PLOWMAN ET AL.

**Examiner**

Michael Borin

**Art Unit**

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 13 and 31-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13 and 31-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***Status of Claims***

1. Amendment filed 06/03/2004 is acknowledged. Claims 1-12,14-30 are canceled. Claims 31-35 are added. Claims 13,31-35 are pending. The claims, as amended, are limited to polypeptide comprising SEQ ID No. 73.
2. Traverse of restriction requirement is noted. The restriction was made final in the previous Office action. Further, the claims directed to non-elected inventions are canceled by applicant.

Applicant's arguments have been fully considered and were deemed persuasive-in-part. Rejections and/or objections not reiterated from previous Office action are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

***Priority***

3. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is not granted. As acknowledged by applicant in this response, the provisional application does not recite a polypeptide comprising SEQ ID NO 73: the disclosure of the provisional application is limited to partial sequence, SEQ ID No. 260. Thus, the provisional applications upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for the elected SEQ ID NO 73.

***Claim Rejections - 35 U.S.C. § 101***

4. Claim 13 is rejected under 35 U.S.C. § 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

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The claim is drawn to method of identifying a modulator of polypeptide SEQ ID No. 73 by expressing the polypeptide in a cell, adding a test compound and monitoring changes in cell properties.

Since neither a modulator of polypeptide SEQ ID No. 73 is disclosed, nor a utility for such particular modulator is addressed, the utility of the method as claimed relies on the utility of polypeptide SEQ ID No. 73 itself. Applicant clarifies in the response filed 06/03/2004 that the claimed polypeptide SEQ ID No. 73 is '>99% identical' to ubiquitin specific protease NP\_115971.1; the latter is posted in NCBI database.

Examiner agrees that due to its high sequence similarity polypeptide SEQ ID No. 73 can be viewed as having same activity as ubiquitin specific protease NP\_115971.1. The issue then is what is the utility of the referenced ubiquitin specific protease NP\_115971.1. The abstract is silent about utility of the referenced polypeptide. The title of the abstract refers to a gene encoding a novel ubiquitin specific protease and potential participation of the gene in human testes development; however, there is no information related to the utility of NP\_115971.1 polypeptide itself. Specification addresses polypeptide SEQ ID No. 73 as cysteine protease of UCH2b family. Search of prior art databases did not reveal information on this particular UCH2b family. As to the broader ubiquitin hydrolase family, UCH2, it is broadly defined by its ability to remove ubiquitin<sup>2</sup> which does not directly translate into a particular utility. Thus, examiner fails to identify a demonstrated utility for NP\_115971.1 polypeptide, and consequently, for its homologs, and, furthermore, its modulators.

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<sup>1</sup>Note that the assertion of applicant about >99% identity of SEQ ID No. 73 to NP\_115971 is incorrect: the referenced sequence is almost identical not to the full length SEQ ID No. 73, but only to its C-terminal fragment beginning from residue 331 of SEQ ID No. 73 - see alignment provided by applicant.

<sup>2</sup>See, e.g., Falquet L. (Database EMBASE, DN 1995353448 . cDNA cloning of a human 100 kDa de-ubiquitinating enzyme: The 100 kDa human de-ubiquitinase belongs to the ubiquitin C-terminal hydrolase family 2 (UCH2). FEBS Letters, (1995) 376/3 (233-237)).

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As for assertions of presence of certain domains in SEQ ID No. 73, such as protease domain, calcium binding domains, the presence of a given motif within a protein sequence does not establish preponderance of evidence that the protein would, in fact, have the function associated with the motif.

Therefore, the invention as claimed requires further substantial research as thus lacks a substantial utility.

***Claim Rejections - 35 USC § 112, first paragraph.***

5. Claims 13, 31-35 are also rejected under 35 U.S.C. §112, first paragraph. Specifically, since the claimed invention is not supported by either a credible asserted utility or a well established utility, one skilled in the art would not know how use the claimed invention.

6. Claims 13, 31-35 are rejected under 35 U.S.C. 112, first paragraph, because the specification is not enabling. The claims are amended to state that modulators of protease polypeptide are identified by effect of a test substance on either cell phenotype, or cell proliferation, or cell differentiation of cells expressing polypeptide SEQ ID 73. There is no demonstrated specific relationship between a ubiquitin specific hydrolase in general, or polypeptide SEQ ID No 73 (which is, allegedly, a ubiquitin specific protease) in particular, and the recited cell features. On the other hand, cell phenotype, cell proliferation, or cell differentiation depend on myriads of various factors and an unspecified change in these cell features is not at all indicative of modulation of activity of a particular enzyme. For example, subjecting cells to a particular inhibitor, e.g., inhibitor of plasma membrane Ca channels, will alter both cell phenotype and cell proliferation, but will not reflect modulation of a ubiquitin specific hydrolase of UCH2b family. Therefore, In view of the above, it is the Examiners

position that with the insufficient guidance and working examples and in view of unpredictability and the state of art one skilled in the art could not make and/or use the invention with the claimed breadth without an undue amount of experimentation.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

a shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (571) 272-0722.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0549.

8/13/04  
mlb

MICHAEL BORIN, PH.D  
PRIMARY EXAMINER

